EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF
WEST VIRGINIA AT CHARLESTON

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IN RE: ETHICON, INC., : Master File No.
PELVIC REPAIR SYSTEM : 2:12-MD-02327
PRODUCTS LIABILITY : MDL 2327
LITIGATION :

THIS DOCUMENT RELATES TO CASE CONSOLIDATION:
Terreski Mullins, et al., v. Ethicon, Inc., et al.
Case No. 2:12-CV-02952

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September 17, 2015

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Oral deposition of ANNE HOLLAND WILSON, MBA, held in the offices of Riker Danzig, 500 Fifth Avenue, New York, New York 10110, commencing at 9:20 a.m., on the above date, before Margaret Peoples, a Registered Professional Reporter and Notary Public in and for the States of Pennsylvania, New York and Connecticut.

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ANNE HOLLAND WILSON, after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. COMBS:

Q. Could you state your name for the record.

A. Anne Holland Wilson.

Q. Ms. Wilson, what's your business address?

A. 7500 Rialto Boulevard, Austin, Texas.

Q. How many times have you been deposed before?

A. Once.

Q. Prior to the deposition, did Mr. Wallace explain to you the ground rules of the deposition, and that I don't need to go back over those?

MR. WALLACE: I'll object

Q. Okay. Well, I just want to make sure that I understand.

I mean, it's my understanding that the process by which you do an audit would be very different than the process by which you prepared this report and the opinions contained in this report.

Is that correct?

MR. WALLACE: Objection to form.

THE WITNESS: Audits use one set of skills. Expert report uses some of those skills, but they're not all the same.

I used the sum of my knowledge as a consultant in risk management, auditing, GLPs, design controls, 15 years of work experience, 15 years of business ownership, consultants to come up with my report.

So you can't single out auditing.

A. Due Diligence Project Tomlin Checklist [ph]. I don't recall hearing that at all.

Q. Other than that, do you believe that you had all of the risk-related documents for TVT?

A. To the best of my knowledge, I asked for.

Q. Your assumption is that you have all.

A. Yeah. My assumption is I do.

Q. And if there are any you didn't have, you tried to get them.

A. Absolutely.

Q. That was part of what you were doing in this process, was trying to assemble all of the risk-related documents in order to form the basis for your opinion?

A. Right. I focused on the design.

Q. In the United States, is design control governed by 21 CFR 820?

A. 820.30, in fact.

Q. Ms. Wilson, you told us about 21 820.30.

What is that?

A. I believe the title is "Design Controls" of the Quality System Regulations.

Q. And is 21 CFR 820 the section of federal regulations that are related to medical devices?

A. There are many things related to medical devices, so that is a subset.

Q. Is it the subset that involves quality system regulations?

A. Correct.

Q. And so, for example --

MR. WALLACE: You have sort of half a question pending. So I'll just note an objection and just ask you to restart.

MR. COMBS: Okay. We'll mark this as Exhibit 4.

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Like right now, does the FDA require a medical device manufacturer to comply with ISO 13485?

MR. WALLACE: Object to form.

THE WITNESS: They -- that's apples and oranges. That isn't peaches and cream.

BY MR. COMBS:

Q. Okay.

A. The FDA has FDA stuff. EU, Canada, many other countries accept 13485. So that question doesn't make any sense to me.

Q. So I'll try it again. Here's the question.

Does the FDA require compliance to ISO 13485?

A. For products distributed within the U.S. by U.S. medical -- no, they do not.

They do have harmonized risk procedures to ISO 14971, however.

Q. Is there an FDA reg that

C E R T I F I C A T E

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

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Margaret Peoples, RPR

Dated: September 17, 2015

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